

REMARKS

Claims 1-5, 8-70 and 76-103 are now pending in the application. Claims 10, 11, 22, 25, 26, 36, 49, 52, 53, 64, 65, and 68 have been amended into independent form. Claim 44 is canceled by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-5, 12-13, 15, 17, 21, 23-24, 32-35, 40-41, 44, 48 and 50-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen (U.S. Pat. No. 5,397,329) in view of Kraus (U.S. Pat. No. 3,918,440). Claims 1, 8-9, 14, 16, 19-20, 32, 41-43, 46-47, 59-63 and 67 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen in view of Vilsmeier (U.S. Pat. No. 6,351,659), and further in view of Kraus. Claims 18, 37-39, 45 and 91-93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen in view of Kraus, and further in view of Reed (U.S. Pat. No. 5,968,047). Claims 31 and 58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen in view of Vilsmeier and Kraus, further in view of Franck et al. (U.S. Pat. No. 6,273,896). These rejections are respectfully traversed.

Allen is directed to fiducial implants 10 that are to be maintained within the anatomy over an extended period of time. See, Allen, col. 5, Ins. 11-44. The fiducial implant 10 includes a screw anchor 14 having a polygonal recess 16 driving portion to receive an allen wrench to drive the screw anchor. Allen describes that a cross-shaped receptor or a single groove driving portion has less symmetrical integrity than the allen

wrench design and disparages such designs and prefers the polygonal recess. See, Allen col. 7, lines 55-61. Allen further discloses that a robot arm 34, whose base is chosen as an origin, can include a sensor 40 to sense the fiducial implants in the skull as the arm is moved over the skull. The position of the arm is determined by detecting rotation and movement of the joints 42 of the arm 74.

Vilsmeier discloses two members, the first being a landmark prominence 70 and the second being a landmark prominence 80. Both of the landmark prominences can be interconnected with a fastener 90 that is stuck to a patient. The first landmark prominence 70 can be imaged, while the second landmark prominence 80 includes a bowl with a funnel that tapers to a tip. The two landmark prominences must be interchanged at various times because the landmark prominence 70 is imaged and only the landmark prominence 80 allows access of a surgical instrument. Both landmark prominences, however, must be interconnected with the fastener 90 to hold the landmark prominences relative to the patient.

Kraus is directed to a device for promoting formation of bone material in a region of bone, via the application of an A.C. signal. Kraus discloses bone screws 12 that include a hexagonal socket 25 and a widened portion 26 defined below the hexagonal socket 25. A locking element 18 locks a wire relative to the screw 12 to provide a current to the screw 12.

Reed is directed to fixation devices, such as bone plates and bone screws. See Reed, Abstract. A bone screw 110 can include an aperture 112 to accommodate a suture 114.

Finally, Franck et al. is directed to a stereotactic surgery system that includes a scanning frame and plurality of scanning markers that can be interconnected therewith. See Franck et al., Abstract.

Independent Claim 1 recites "a conical receptacle . . . integrated with the imagable fiducial locator head and configured with a base at a surface of the locator head and an apex at a center of the locator head to permit access to a center of the imagable fiducial locator head." Applicants respectfully submit that the combination of Allen and Kraus alone does not anticipate or fairly render obvious each of the elements of independent Claim 1. Applicants respectfully submit that neither Allen, nor Krause at least disclose or fairly render obvious a conical receptacle as recited in independent Claim 1. In this regard, neither Allen nor Kraus disclose a conical receptacle.

Further, Applicants respectfully submit the combination of Allen, Vilsmeier, and Kraus also fails to anticipate or fairly render obvious independent Claim 1. As previously argued in the amendment filed June 22, 2007, Applicants respectfully submit that a combination of Allen and Vilsmeier renders both inoperable, at least because the inclusion of the bowl of Vilsmeier would render inoperable the polygonal opening 16 of Allen as a driving portion. Although the Office has added Kraus, Applicants respectfully submit that Kraus does not at least overcome the failing of both Allen and Vilsmeier regarding "a conical receptacle . . . configured with a base at a surface of the locator head and an apex at a center of the locator head to permit access to a center of the imagable fiducial locator head." Even assuming that Kraus can be combined with Allen and Vilsmeier, at least to counter the inoperability of the combination of Allen and Vilsmeier, Kraus discloses that a hexagonal socket is formed in the bone screw which is

terminated by a widened portion 26. The configuration of Kraus is opposed to a conical receptacle, as recited in independent Claim 1, because the socket 25 of Kraus appears to have substantially perpendicular walls (See, Kraus, Fig. 4) and the widened lower portion 26. This is not conical at least because it appears to have parallel sides near the surface. Therefore, independent Claim 1, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Independent Claim 32 originally and currently recites "a conical receptacle." As discussed in relation to independent Claim 1, Applicants respectfully submit that the combination of only Allen and Kraus does not render obvious each of the elements of independent Claim 32, at least because none of the references disclose a conical receptacle. Moreover, regarding the rejection including Vilsmeier, Applicants maintain the argument of inoperability of the combination of Allen and Vilsmeier as discussed above.

Independent Claim 32 is also amended to recite "a bone screw shaft that extends outward from and is formed unitary and single-piece with the imagable fiducial locator head," which is not disclosed or fairly rendered obvious by the combination of Allen, Vilsmeier, and Kraus. Vilsmeier requires that a fastener 90 be connected to a patient and that two different landmarks be interconnected therewith. Therefore, Vilsmeier is actually contrary to having a single piece bone screw and locator head of independent Claim 32. At least for this additional reason, the combination of Allen and Vilsmeier is improper in light of independent Claim 32. Therefore, independent Claim 32, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Independent Claim 59 has been amended to recite “driving directly into a bone of a patient a fiducial marker device . . . forming an apex of the conical receptacle at the center; accessing the apex with the instrument by moving the instrument towards the apex while the instrument is substantially angled relative to an axis along the height of the integral conical receptacle.” As discussed above, Vilsmeier requires two landmarks that are interconnected with a single fastener 90, where one landmark has a bowl for receiving an instrument and the other is imagable. Allen requires that a fiducial is driven into a bone and maintained there and that a sensor is needed to locate the fiducial, rather than mating an instrument with a receptacle. Therefore, Applicants respectfully submit that the combination of Allen and Vilsmeier renders a combined construct inoperable. If the marker of Allen is fixed permanently to a bone then a landmark to be touched with an instrument could not be interchangeably affixed to the fastener, as required by Vilsmeier.

Moreover, Allen and Vilsmeier are contrary to one another regarding a method of using a system. First, Allen discloses and requires that the fiducials be permanently implanted for multiple imaging sessions. Contrary to Allen, Vilsmeier requires that a fastener be positioned onto a patient and two different landmarks be interchangeably connected therewith. Second, Allen discloses that a robotic arm includes a sensor to determine the location of a fiducial through skin. Allen does not disclose direct contact with the fiducial. Contrary to Allen, Vilsmeier discloses that a bowl is contacted with an instrument. Therefore, the combination of Allen and Vilsmeier is improper.

The combination of Kraus with Allen and Vilsmeier does not overcome the failings of Allen or Vilsmeier. Moreover, this combination is also contrary to forming an

apex of a conical receptacle at a center of a head and accessing the apex by moving an instrument at an angle relative to an axis along a height of the conical receptacle, to which Claim 59 is directed. In this regard, Kraus discloses a socket that appears to include substantially parallel sides and a widened portion further within the head. Therefore, independent Claim 59, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Finally, independent Claim 91 recites “a substantially spherical imagable fiducial locator head . . . a receptacle that is sized and shaped for engaging a locator instrument of a positioning system, the receptacle integrated with the imagable fiducial locator head to permit access to a center of the imagable fiducial locator head; and a bone screw shaft that extends outward from the imagable fiducial locator . . . the bone screw shaft including an externally unthreaded portion.” Applicants respectfully submit that none of Allen, Kraus, or Reed anticipate or fairly render obvious a receptacle integrated with the imagable fiducial locator head to permit access to a center of the imagable fiducial locator head, as recited in independent Claim 91. Moreover, Applicants respectfully submit that none of these references, either alone or in combination, anticipate or fairly render obvious a bone screw shaft including an externally unthreaded portion separating an externally threaded portion from an imagable fiducial locator head, also as recited in independent Claim 91. As discussed above, neither Allen, nor Kraus include a receptacle for engaging a locator instrument, as recited in independent Claim 91. Therefore, even assuming that Reed can be combined with either Allen or Kraus, Reed does not overcome the failing of including a receptacle as recited in independent

Claim 91. Therefore, independent Claim 91, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

ALLOWABLE SUBJECT MATTER

The Examiner states that claims 76-90 and 94-103 are allowed. The Examiner also states that claims 10-11, 22, 25-30, 36, 49, 52-57, 64-66 and 68-70 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants thank the Examiner for the indication of allowance of Claims 76-90 and 94-103.

Applicants have amended claims 10, 11, 22, 25, 26, 36, 49, 52, 53, 64, 65, and 68 into independent form to include the limitations of the base claim and any intervening claims. Therefore, claims 10, 11, 22, 25-30, 36, 49, 52-57, 64-66 and 68-70 are now in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated:

January 4, 2008

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